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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/464,377	12/15/1999	MICHAEL R. STALLCUP	13761-726	7454

7590

06/26/2002

VINCENT K YIP
MCCUTCHEN DOYLE BROWN & ENERSON LLP
THREE EMBARCADERO CENTER
SAN FRANCISCO, CA 94111

EXAMINER

PROUTY, REBECCA E

ART UNIT

PAPER NUMBER


1652

DATE MAILED: 06/26/2002

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No. 09/464,377	Applicant(s) Stallcup et al.	
Examiner Rebecca Prouty	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Feb 14, 2002
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
- 4a) Of the above, claim(s) 4-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 39-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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Claims been canceled. Claims 1-38 and newly presented claims 39-47 are still at issue and are present for examination.

Applicants' arguments filed on 2-14-02, paper No. 15, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Applicant's election with traverse of Group I, Claims 1-3 in Paper No. 12 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 4-38 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in Paper No. 12.

Claims 1-3 and 39-47 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification as filed fails to provide support for the current limitations to nucleic acids with particular amounts of

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sequence identity to only nucleotides 1-2100 of SEQ ID NO:1. Nowhere in the specification is the fragment 1-2100 of SEQ ID NO:1 specifically recited as defining applicants invention.

Claims 1-3 and 39-47 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims are directed to a genus of nucleic acid molecules with which are at least 80% (or 90% or 95%) identical to nucleotides 1-2100 of SEQ ID NO:1.

The specification does not contain any disclosure of the function of all nucleic acid molecules with which are at least 80% (or 90% or 95%) identical to nucleotides 1-2100 of SEQ ID NO:1. The genus of nucleic acids that comprise these above molecules is a large variable genus with the potentiality of encoding many different proteins. Therefore, many functionally unrelated DNAs are encompassed within the scope of these claims, including partial DNA sequences. The specification discloses only two species of the claimed genus (i.e., SEQ ID NO:1 and a mutant thereof in Example 8) which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the

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art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Applicants argue that there is no requirement that more than one species be disclosed to support a genus. This is not persuasive because while there may not be any requirement that more than one species be disclosed to support a genus as stated in the written description guidelines, the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus, **A representative number of species means that the species which are**

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adequately described are representative of the entire genus.

Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. Satisfactory disclosure of a representative number depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed. For inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species cannot be achieved by disclosing only one or a few species within the genus. In the instant case the claimed genera of Claims 1-3 and Claims 39-47 includes species which are widely variant in function. The claimed genera include nucleic acids encoding proteins with methyltransferase activity, transcriptional co-activator activity and GRIP-1_c binding activity, nucleic acids encoding polypeptides with only some of these functional characteristics, nucleic acids which do not encode polypeptides but which could be used as probes for SEQ ID NO:1, or as expression modulators, and nucleic acids with no defined functions. As such, neither the description of the structure and function of SEQ ID NO:1 and its mutant nor the disclosure solely

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structural features present in all members of the genus is sufficient to be representative of the attributes and features of the entire genus.

Claims 1-3 and 39-47 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID NO:1, does not reasonably provide enablement for any nucleic acid comprising a sequence 80% (or 90% or 95%) identical to SEQ ID NO:1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The rejection is explained in the previous Office Action.

Applicants argue that the instant claims are enabled as despite the claimed genus being large, each embodiment can be readily identified using the genetic code, synthesized using conventional methods and used in the manner taught in the specification without undue experimentation. This is not persuasive because while each embodiment can be readily identified using the genetic code and synthesized using conventional methods the vast majority of the embodiments encompassed could not be used in the manner taught in the specification for SEQ ID NO:1 without undue experimentation for the reasons previously presented.

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Claims 1-3 are rejected under 35 U.S.C. 102(a) as being anticipated by Chen et al.

Chen et al. teach the cloning and expression of a CARM1 nucleic acid identical to SEQ ID NO:1.

Applicants argue that Chen et al. is not prior art as it was published after the filing date of provisional application 60/112,523. This is not persuasive as the provisional application fails to provide support for the current claim limitations to 80% (or 90% or 95%) identity to specifically nucleotide 1-2100 of SEQ ID NO:1. As such the instant claims cannot be granted the benefit of the filing date of the provisional application.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened

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statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rebecca Prouty, Ph.D. whose telephone number is (703) 308-4000. The examiner can normally be reached on Monday-Friday from 8:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy, can be reached at (703) 308-3804. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

A handwritten signature in black ink, appearing to read 'Rebecca Prouty', with a stylized, flowing script.

Rebecca Prouty
Primary Examiner
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